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October 22, 2003

CERTIFICATE OF MAILING  
37 C.F.R. 1.8

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October 22, 2003

Date

Charles P. Landrum

**MS DD**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/629,329 entitled "METHODS AND COMPOSITIONS USING POLYNUCLEOTIDES AND POLYPEPTIDES OF RANK-ASSOCIATED INHIBITOR (RAIN)" – Bryant G. Darnay*  
*Our reference: UTSC:761US*  
*Client reference: MDA02-072*

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references C1-C16.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/UTSC:761US.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Charles P. Landrum  
Patent Agent  
Reg. No. 46,855

CPL/kmv  
Encl.: as noted

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**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Bryant G. Darnay

Serial No.: 10/629,329

Filed: July 29, 2003

For: METHODS AND COMPOSITIONS  
USING POLYNUCLEOTIDES AND  
POLYPEPTIDES OF RANK-  
ASSOCIATED INHIBITOR (RAIN)

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: UTSC:761US

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October 22, 2003

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*Charles P. Landrum*  
Charles P. Landrum

**INFORMATION DISCLOSURE STATEMENT**

**MS DD**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

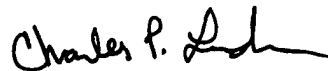
In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/UTSC:761US.

Applicant respectfully requests that the listed documents be made of record in the present case.

Respectfully submitted,



Charles P. Landrum  
Reg. No. 46,855  
Agent for Applicant

FULBRIGHT & JAWORSKI L.L.P.  
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Date: October 22, 2003

Form PTO-1449 (modified)

Atty. Docket No.

UTSC:761US

Serial No.

10/629,329

List of Patents and Publications for Applicant's

Applicant

Bryant G. Darnay

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:

July 29, 2003

Gr up:

Unknown

U.S. Patent Documents

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Foreign Patent Documents

See Page 1

Other Art

See Page 1

## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Bucay <i>et al.</i> , "Osteoprotegerin-deficient mice develop early onset osteoporosis and arterial calcification.," <i>Genes Dev.</i> , 12:1260-1268, 1998.
	C2	Darnay <i>et al.</i> , "Activation of NF- $\kappa$ B by RANK requires tumor necrosis factor receptor-associated factor (TRAF) 6 and NF- $\kappa$ B-inducing kinase," <i>J. Biol. Chem.</i> , 274(12):7724-7731, 1999.
	C3	Darnay <i>et al.</i> , "Characterization of the intracellular domain of receptor activator of NF- $\kappa$ B (RANK)," <i>J. Biol. Chem.</i> , 273(32):20551-20555, 1998.
	C4	Dougall <i>et al.</i> , "RANK is essential for osteoclast and lymph node development," <i>Genes Dev.</i> , 13:2412-2424, 1999.
	C5	Fujikawa <i>et al.</i> , "The human osteoclast precursor circulates in the monocyte fraction," <i>Endocrinol.</i> , 137(9):4058-4060, 1996.
	C6	GenBank Accession No. AB028863
	C7	GenBank Accession No. AF132963
	C8	Hofbauer, "The roles of osteoprotegerin and osteoprotegerin ligand in the paracrine regulation of bone resorption," <i>J. Bone Miner. Res.</i> , 15(1):2-12, 2000.
	C9	Ishida <i>et al.</i> , "Protein that makes sense in the Argentine ant," <i>Naturwiss.</i> , 89:505-507, 2002.
	C10	Kong <i>et al.</i> , "OPGL is a key regulator of osteoclastogenesis, lymphocyte development and lymph-node organogenesis," <i>Nature</i> , 397:315-323, 1999.

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EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.



Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

UTSC:761US

Serial N .

10/629,329

Applicant

Bryant G. Darnay

Filing Date:

July 29, 2003

Group:

Unknown

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C11	Li <i>et al.</i> , "RANK is the intrinsic hematopoietic cell surface receptor that controls osteoclastogenesis and regulation of bone mass and calcium metabolism," <i>Proc. Natl. Acad. Sci., USA</i> , 97(4):1566-1571, 2000.
	C12	Mizuno <i>et al.</i> , "Severe osteoporosis in mice lacking osteoclastogenesis inhibitory factor/osteoprotegerin," <i>Biochem. Biophys. Res. Commun.</i> , 247:610-615, 1998.
	C13	Okahashi <i>et al.</i> , "Osteoclast differentiation is associated with transient upregulation of cyclin-dependent kinase inhibitors p21WAF1/CIP1 and p27KIP1," <i>J. Cell Biochem.</i> , 80(3):339-345, 2001.
	C14	Pullen <i>et al.</i> , "CD40 signaling through tumor necrosis factor receptor-associated factors (TRAFs)," <i>J. Biol.Chem.</i> , 274:14246-14254, 1999.
	C15	Scheven <i>et al.</i> , "In vitro osteoclast generation from different bone marrow fractions, including a highly enriched haematopoietic stem cell population," <i>Nature</i> , 321:79-81, 1986.
	C16	Takayanagi <i>et al.</i> , "Induction and activation of the transcription factor NFATc1 (NAFT2) integrate RANKL signaling in terminal differentiation of osteoclast," <i>Dev. Cell</i> , 3(6):889-901, 2002.

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